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EXAMINER	
KAUR, GURPREET	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,275	FUJIWARA ET AL.	
	Examiner	Art Unit	
	GURPREET KAUR	1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/27/2010 and 1/03/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 16-43 are pending in the application.

Status of the Rejections

2. Examiner has attached new PTO892 form to list the Schibli reference correctly as EP1167538.

The rejection of claim 41 under 35 USC 112, sixth paragraph is withdrawn in view of applicant's amendment.

All other rejections from the previous office action are maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 16, 17, 19, 21-24, 28-33, 35, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schibli (EP1167538, examiner is using US 2004/0043477 as English translation) and in view of Taniike et al. (U.S. Pub. No. 2001/0006149) and as evidenced by Lin et al (2002/0048532).

Regarding claim 16, Schibli teaches a biosensor comprising:

a first electrode system (electrodes 8 and 11) thus comprising first analysis portion. The first electrode further comprises paste containing enzyme which reacts with glucose with the help of mediator (see figure 2 and paragraph 0064); and

a second electrode system (electrodes 9 and 10) thus comprising second analysis portion and contains the same paste as in first electrode system (see figure 2 and paragraph 0064) .

voltage is applied to both the electrode system to measure current (see paragraphs 0002 and 0065).

Schibli does not explicitly indicate that in the second electrode system the mediator is disposed only on the counter electrode and not on the working electrode.

However, Taniike et al. teaches a biosensor wherein the counter electrode comprises only mediator and working electrode comprises enzyme only (see claim 1 and paragraphs 0010 and 0011) because mediator being primarily on the counter electrode prevents the reaction occurring at the counter electrode and thus preventing reaction at the counter electrode from becoming a rate determining step at high sample concentration to obtain linear response current (see paragraph 0050).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to dispose mediator only on the counter electrode as taught by Taniike in the second electrode system of Schibli because mediator being primarily on the counter electrode prevents the reaction occurring at the counter electrode and thus preventing reaction at the counter electrode from becoming a rate determining step at high sample concentration to obtain linear response current (see paragraph 0050).

Either of the electrodes (9 or 10) can work as working electrode or counter electrodes in the second electrode system. The terms working and counter merely specify the intended use of the electrode and do not infer any structural distinction to the electrodes. Intended use need not be give further due consideration in determining patentability of an apparatus.

Furthermore, claim 16 recites the limitation in the first analysis portion blood is measured and in the second analysis portion Hct value of the blood is measured is just an intended use of the device. The cited prior art teaches all of the positively recited structure of the claimed apparatus. The Courts have held that a statement of intended use in an apparatus claim fails to distinguish over a prior art apparatus. See *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and

Hewlett-Packard Co. V. Bausch and Lomb, Inc., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP §§ 2114 and 2173.05(g)).

Moreover, Lin et al. teaches an electrode strip which can measure concentration of hemoglobin and hematocrit in a liquid sample by applying voltage to the electrode system and measuring the current related to hemoglobin and hematocrit value (see paragraphs 0007 and 0039).

4. Regarding claim 17, sensor capable of correction component value based on measured Hct value is an intended use language. The limitation does not recite any structural features of the device and the cited prior art teaches all of the positively recited structure of the claimed apparatus. The Courts have held that a statement of intended use in an apparatus claim fails to distinguish over a prior art apparatus. See *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP §§ 2114 and 2173.05(g)).

5. Regarding claim 19, Schibli teaches a capillary channel (20) comprising second analysis portion (electrodes 9 and 10) which is on upstream side and first analysis portion (electrodes 8 and 11) is downstream from the flow of the blood (see figures 1, 2 and 3).

6. Regarding claims 21, 22, 31 and 32, Schibli teaches paste containing ferrocene mediator is applied to one electrode of each of the pairs (see paragraph 0064) and Taniike et al. teaches mediator is potassium ferricyanide (see paragraph 0036).

7. Regarding claims 23 and 24, Taniike et al. teaches working electrode is coated with carboxymethylcellulose (polymeric material) (see paragraphs 0032 and 0037).

8. Regarding claim 28, Schibli teaches the first electrode system comprises of two electrodes, thus either of electrodes (8 or 11) can work as working electrode or counter electrodes. The terms working and counter merely specify the intended use of the electrodes and do not infer any structural distinction to the electrodes. Intended use need not be give further due consideration in determining patentability of an apparatus.

9. Regarding claims 33 and 35, Schibli teaches an insulating substrate (base plate 1) (see paragraph 0012) comprises electrodes 8 to 11 i.e. first and second analysis portion and capillary channel (20) has supply inlet (16) to introduce body fluid (blood) (see paragraphs 0044, 0046, 0017 and figure 2). Schibli teaches a capillary channel

(20) comprises second analysis portion (electrodes 9 and 10) which is on upstream side and first analysis portion (electrodes 8 and 11) is downstream from the flow of the blood (see paragraph 0042 and figures 1, 2 and 3).

10. Regarding claim 37 and 38, the component to be measured is glucose with glucose oxidase (see paragraphs 0048 and 0064).

11. Regarding claims 29 and 30, Schibli teaches first and second analysis portion which are comprised of pair of electrodes (see claim 16 above) and furthermore the electrodes are made up of platinum which is the same material used in applicant's electrodes (see paragraph 0088). The limitations reciting where one of electrode in the first electrode system serve as counter electrode or working electrode in the second electrode is just an intended use of the electrode in the first electrode system. The cited prior art teaches all of the positively recited structure and material composition of the claimed apparatus. The Courts have held that a statement of intended use in an apparatus claim fails to distinguish over a prior art apparatus. See *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V.*

Bausch and Lomb, Inc., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP §§ 2114 and 2173.05(g)).

12. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schibli , Taniike and Lin as applied to claim 16 above, and further in view of Lewandowski et al. (U.S. Pat. No. 4,897,162).

Regarding claims 25-27 Schibli teaches voltage is applied to electrode system to measure current and Taniike teaches voltage of 500 mv is applied to electrode system or any voltage can be applied to enable oxidation of electron mediator.

Both Schibli and Taniike do not explicitly indicate voltage is 1 to 10 V.

However, Lewandowski teaches a glucose sensing apparatus wherein the pulse voltage of 0.8 to 2.5 Volts can be applied to the electrode system to measure the glucose levels and such variation of applied voltage gives higher catalytic activity, better stability and better control of background current (see col. 5, ll. 3-29).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the voltage range applied to electrode system of Schibli as taught by Lewandowski because applied pulse voltage gives higher catalytic activity, better stability and better control of background current (see col. 5, ll. 3-29).

13. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schibli, Taniike and Lin as applied to claims 16 above, and further in view of Hsu et al. (U.S. Pub. No. 2004/0134779).

Regarding claim 34, Schibli teaches an insulating substrate (base plate 1) (see paragraph 0012) comprises electrodes 8 to 11 i.e. first and second analysis portion and capillary channel (20) has one supply inlet (16) to introduce body fluid (blood) (see paragraphs 0044, 0046, 0017 and figure 2). Schibli teaches a capillary channel (20) comprises second analysis portion (electrodes 9 and 10) which is on upstream side and first analysis portion (electrodes 8 and 11) is downstream from the flow of the blood (see paragraph 0042 and figures 1, 2 and 3).

However, Schibli, Taniike and Lin does not teach branched channel with ends of the branched portions communicating with the analysis portion.

However, Hsu et al. teaches a strip for analyzing the sample wherein the channel is branched into two portions and each portion communicates with a different analysis portion encompassing different set of electrode pairs (see paragraphs 0033 and 0034 and figure 4).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the arrangements of the electrode and channel shape of Schibli as taught by Hsu i.e. arrange the electrodes parallel across the width of the substrate such that branch channel can reach each analysis portion comprised of different set of electrodes because with such an arrangement different analytes can be measured with a sample (see paragraph 0034).

14. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schibli, Taniike and Lin as applied to claim 16 above and further in view of Miyazaki et al. (U.S. Pub. No. 2002/0179442) and Wilsey et al. (U.S. Pat. No. 6,541,216).

Regarding claim 39, Schibli teaches paste containing enzyme and a mediator (see paragraph 0064) applied on the working electrode and Taniike et al. teaches working electrode is coated with carboxymethylcellulose (polymeric material) (see paragraphs 0032 and 0037).

Schibli,Taniike and Lin do not teach reagent layer on the first electrode system is comprised of enzyme stabilizer and crystal homogenizing agent.

However, Miyazaki teaches the reagent layer which is disposed on the electrode system is comprised of amino acid which prevents potassium ferricyanide from being crystallized and further helps reagent layer to be formed smoothly and homogeneously (see figure 11 and paragraph 0131).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to add amino acid into the reagent layer as taught by Miyazaki into the reagent layer as taught by combined teachings of Schibli and Taniike because amino acid prevents potassium ferricyanide from being crystallized and further helps reagent layer to be formed smoothly and homogeneously (see paragraph 0131).

Schibli,Taniike, Lin and Miyazaki do not teach reagent layer on the first electrode system is comprised of enzyme stabilizer.

However, Wilsey et al. teaches test strip wherein the reagent contains stabilizer for the enzyme because stability of the enzyme in turns affects the enzyme's activity

which is needed to catalyze the reaction between the mediator and the analyte of interest (see col. 9 ll.6-35).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to add enzyme stabilizer into the reagent layer as taught by Wilsey into the reagent layer as taught by combined teachings of Schibli, Taniike and Miyazaki because stabilized enzyme affects the enzyme's activity which is needed to catalyze the reaction between the mediator and the analyte of interest (see col. 9 ll.6-35).

15. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schibli , Taniike and Lin as applied to claim 16 above, and further in view of Ikeda et al. (U.S. Pat. No. 5,582,697).

Regarding claim 40, Schibli and Taniike do not teach a biosensor further comprises a detection electrode.

However, Ikeda teaches a biosensor comprised of third electrode located further away from the sample supply port and is used for detecting liquid (blood) to indicate if the sample liquid supplied has covered the entire reaction layer (see col. 5, ll. 60-67 over to col. 6, ll.1-2).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to add a detecting electrode as taught by Ikeda to the sensor assembly of Schibli because a detecting electrode can ensure if the sample liquid has covered the entire reaction layer (see col. 5, ll. 60-67 over to col. 6, ll.1-2).

16. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schibli, Taniike and Lin as applied to claim 16 above, and further in view of Ikeda et al. (U.S. Pat. No. 5,582,697).

Regarding claims 41 and 42, Schibli and Taniike teaches measuring the current of the electrode system by applying voltage but do not explicitly indicate the measuring means.

However, Ikeda teaches biosensor (B) is connected to measuring device (A) which holds the biosensor, a current/voltage circuit, an A/D converting circuit for applying voltage and measuring current to the electrodes and a controller 28 including a microcomputer which is capable of calculating and correcting values (see figures 7 and 8).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to incorporate the measuring device of Ikeda with Schibli biosensor to apply voltage, measure current, calculate and correct values with the same measuring device (see figures 7 and 8) and moreover make a compact device.

17. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schibli, Taniike, Lin and Ikeda as applied to claim 41 above, and further in view of Lewandowski et al. (U.S. Pat. No. 4,897,162).

Regarding claim 43, Schibli teaches voltage is applied to electrode system to measure current and Taniike teaches voltage of 500 mv is applied to electrode system or any voltage can be applied to enable oxidation of electron mediator.

Schibli, Taniike and Ikeda do not explicitly indicate voltage is 1 to 10 V.

However, Lewandowski teaches a glucose sensing apparatus wherein the pulse voltage of 0.8 to 2.5 Volts can be applied to the electrode system to measure the glucose levels and such variation of applied voltage gives higher catalytic activity, better stability and better control of background current (see col. 5, ll. 3-29).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the voltage range applied to electrode system of Schibli as indicated by Lewandowski because applied pulse voltage gives higher catalytic activity, better stability and better control of background current (see col. 5, ll. 3-29).

18. Claims 16, 18, 20 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshioka et al. (U.S. Pat. No. 5,264,103) and further in view of Taniike et al. (U.S. Pub. No. 2001/0006149) and as evidenced by Lin et al (2002/0048532).

Regarding claim 16, Yoshioka teaches a biosensor comprising:

a first electrode system (electrodes 6 and 7) thus comprising first analysis portion. The first electrode further comprises reaction layer, 5 containing enzyme which reacts with glucose with the help of mediator (see figure 3 and col. 5, ll. 23-29); and

a second electrode system (electrodes 8 and 9) thus comprising second analysis portion and is covered with reference layer, 25 containing potassium ferricyanide (mediator) (see figure 3 and col. 6, ll. 9-13).

voltage is applied to both the electrode system to measure current (see col. 6, ll. 33-46 and 56-61).

Yoshika does not explicitly indicate that in the second electrode system the mediator is disposed only on the counter electrode and not on the working electrode.

However, Taniike et al. teaches a biosensor wherein the counter electrode comprises only mediator and working electrode comprises enzyme only (see claim 1 and paragraphs 0010 and 0011) because mediator being primarily on the counter electrode prevents the reaction occurring at the counter electrode and thus preventing reaction at the counter electrode from becoming a rate determining step at high sample concentration to obtain linear response current (see paragraph 0050).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to dispose mediator only on the counter electrode as taught by Taniike of the second electrode system Yoshika because mediator being primarily on the counter electrode prevents the reaction occurring at the counter electrode and thus preventing reaction at the counter electrode from becoming a rate determining step at high sample concentration to obtain linear response current (see paragraph 0050).

Either of the electrodes (6 or 8) can work as working electrode or counter electrodes. The terms working and counter merely specify the intended use of the electrode and do not infer any structural distinction to the electrodes. Intended use need not be give further due consideration in determining patentability of an apparatus.

Limitations reciting in the first analysis portion blood is measured and in the second analysis portion Hct value of the blood is measured is just an intended use of

the device. The cited prior art teaches all of the positively recited structure of the claimed apparatus. The Courts have held that a statement of intended use in an apparatus claim fails to distinguish over a prior art apparatus. See *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP §§ 2114 and 2173.05(g)).

Moreover, Lin et al. teaches an electrode strip which can measure concentration of hemoglobin and hematocrit in a liquid sample by applying voltage to the electrode system and measuring the current related to hemoglobin and hematocrit value (see paragraphs 0007 and 0039).

19. Regarding claim 18, Yoshioka teaches in figure 3 that all the electrodes 6 to 9 are printed on substrate 1 along with their contacts. Electrodes 8 and 8 are spaced apart from each other and are coplanar (see figures 2, 3 and col. 5, ll. 4-15).

20. Regarding claim 20, Yoshioka teaches sensor is comprised of passage, 18 through which liquid passes and electrodes (8, 9) are arranged in serial with respect to the flow of fluid (see figures 2 and 3).

21. Regarding claim 36, Yoshioka teaches sensor is comprised of insulating substrate (1), a spacer (3) and a cover (4) (see figure 2). The first (electrodes 6, 7) and second (electrodes 8, 9) analysis portion are formed on the insulating substrate (see figure 2) with a supply port (23) and cover (4) is disposed on the substrate via the spacer (3) (see figure 2).

Response to Arguments

Applicant's arguments filed 12/03/2010 have been fully considered but they are not persuasive.

Applicant argues on page 8 of Remarks section that the identification/function of the working electrode and counter electrode as claimed cannot be construed as merely intended use of the electrodes as they play specific and different role in the sensor.

Examiner agrees with applicant's argument regarding electrodes have specific and different role in the sensor such that appropriate voltage can be applied across the electrodes. However, the terms working and counter merely specify the intended use of the electrodes. Moreover, the cited reference Schibli teaches all the conducting structure (electrodes 8 to 11) are made up of gold (see paragraph 0052) and current is measured across the pair of electrodes (see paragraph 0064 and 0065) and furthermore the pair of electrodes can be used as reference pair to obtain reference

measurements as well (see paragraph 0068), thus it would be obvious from the teachings of Schibli since all the electrodes are constructed from same material, such as gold then either of the electrodes can play the role of "working" or the "counter" electrode to measure current across the electrodes to determine the concentration of the substance in the sample.

Applicant further argues on page 9 that Schibli in view of Taniike does not teach hematocrit analyzer portion. Examiner like to reassert that the claim 16 is to a biosensor and cited prior art teaches all the structural limitations of the biosensor. Applicant argues that cited prior art does not teach "hematocrit" analyzing portion but Schibli teaches two analyzing portion (see figure 2) which are considered structural limitations to the claim. Schibli further teaches each analyzing portion can measure different substances in the body liquid sample (see paragraph 0008), thus Schibli device is capable of measuring hematocrit.

Applicant argues on page 9 regarding the justification provided by the Examiner to combine teachings of Taniike and Schibli. Applicant alleges the teachings were taken in hindsight and one of ordinary skill in the art would have concluded to use Taniike reference to isolate enzyme from the counter electrode rather than to dispose mediator only on the counter electrode. However, if that was the case Taniike would have consider leaving the mediator and enzyme on the working electrode, rather than disposing the enzyme on the working electrode and mediator on the counter electrode. Moreover, Taniike further teaches in paragraph 0051 keeping the enzyme separated from the mediator lowers the blank response and current response does not change

after a long-time storage. Thus, from the teachings of Taniike one would have concluded to keep the enzyme separated from the mediator.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GURPREET KAUR whose telephone number is (571)270-7895. The examiner can normally be reached on Monday-Friday 9:00-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ula C. Ruddock can be reached on (571)272-1481. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. K./
Examiner, Art Unit 1759

/Ula C Ruddock/
Supervisory Patent Examiner, Art Unit 1729